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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,310	08/29/2001	Carl Risinger	524592001900	7722

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/942,310

Applicant(s)

RISINGER ET AL.

Examiner

Diana B. Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***ELECTION/RESTRICTION***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to methods for "determining a human's capacity to metabolize a substrate of a CYP2D6 enzyme," classified in, at least for example, class 435, subclass 6.
  - II. Claims 2-8, drawn to oligonucleotides and primer pairs, classified in, at least for example, class 536, subclasses 24.31 and 24.33.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Invention II may be employed in a materially different process, such as methods of detecting the presence of a CYP gene, methods of cloning and expressing a CYP gene, etc.

**Election Requirement Applicable to Groups I and II**

3. Group I is drawn to methods in which one of eight different combinations of CYP2D6 polymorphisms must be detected. Molecules comprising each of the different combinations have a different nucleotide sequence, and therefore a different structure. Further, the specification does not indicate that molecules including each of these different combinations are functionally equivalent to one another. Rather, the specification suggests that each haplotype may be associated with a different metabolic

phenotype. Accordingly, Group I encompasses detection of eight structurally and functionally distinct molecules, which molecules are not, e.g., obvious variants that may be substituted one for the other. Therefore, **if Group I is elected, Applicant is further required to elect a single one of the 8 combinations of polymorphisms recited in claim 1.**

**This is not an election of species.** Applicant is advised that examination will be restricted to only the elected combination of polymorphisms.

4. Group II encompasses claims drawn to oligonucleotides, primer pairs, and combinations thereof. As claims 5-8 encompass kits including both combinations of primer pairs and combinations of sequencing oligonucleotides, claims 5-8 link claims 2-8 together into a single Group. However, claims 2-8 encompass a multitude of different combinations of primer pairs and oligonucleotides. Each combination has a different structure, as each encompasses a different group of nucleotide sequences. Further, each combination has a different function, as each combination of molecules serves to amplify and detect a different set of polymorphisms. As discussed in paragraph 3, above, the various combinations of polymorphisms of the Invention are structurally and functionally distinct. Accordingly, **if Group II is elected, Applicant is further required to elect** a single one of the combinations of primer pairs and sequencing oligonucleotides encompassed by the claims. Specifically, Applicant should elect one combination of "at least three" primer pairs as set forth in claim 4, as well as one set of "sequence determination oligonucleotides" corresponding to the elected combination of

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primer pairs (see, e.g., claims 5-8). Applicant should clearly identify the SEQ ID Nos corresponding to the elected combination of molecules.

**This is not an election of species.** Applicant is advised that examination will be restricted to only the elected combination of molecules.

5. Because Inventions I-II are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-II, as well as the numerous distinct combinations of polymorphisms of Group I and the multitude of different functionally and structurally distinct combinations of molecules of Group II, require different sequence and text searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

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703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", with a long, sweeping horizontal line extending to the right.

Diana B. Johannsen  
December 15, 2002